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GB 2057269 A GB 1286789 A WO 95/07722 A
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(54) Abstract Title
Injection device

(57) An injection device 10 comprises a foot 20 for positioning against the skin 130 of a patient and a body 30 attached to the foot. The body 30 comprises a needle channel 40 and a syringe 50 having a retractable needle 80. On positioning the foot on the skin, the needle extends along the needle channel and enters the skin at an oblique angle. The device is especially useful for injecting depot formulations intramuscularly or subcutaneously.

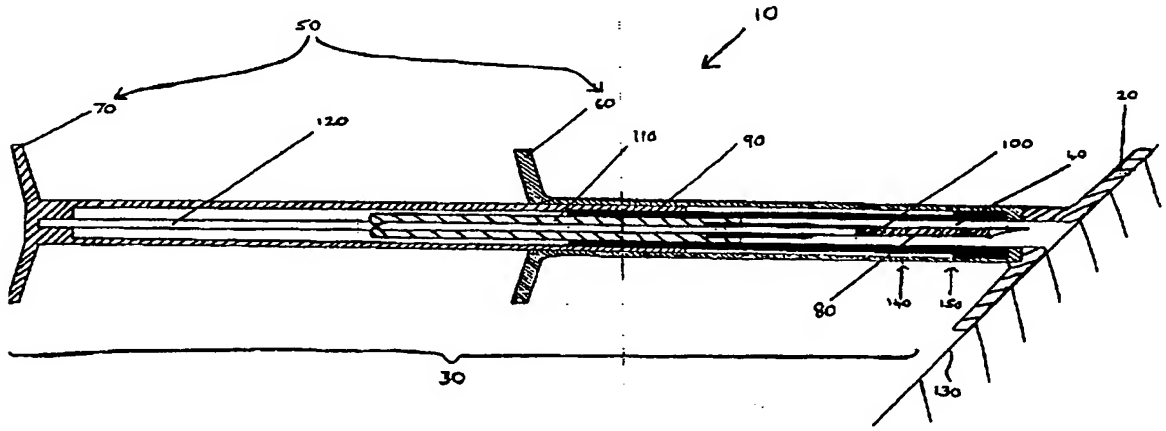

Figure 1

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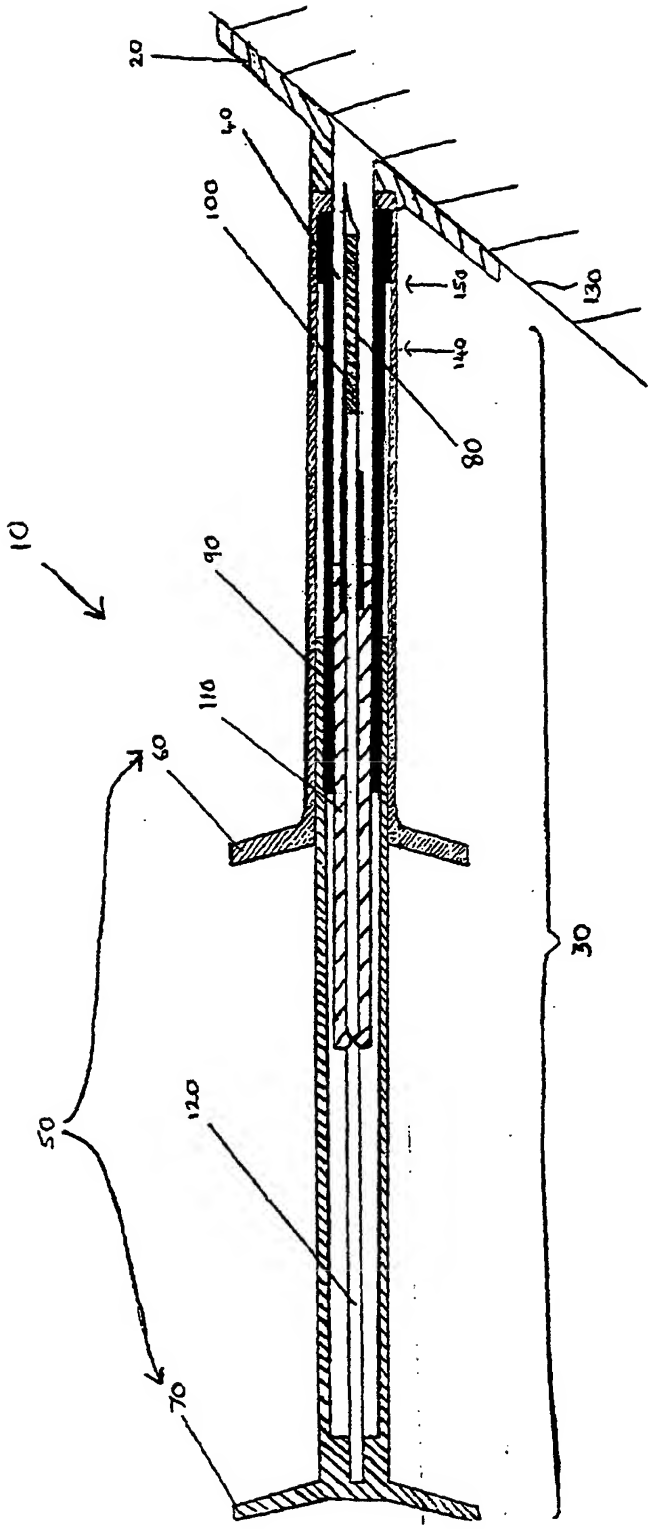

Figure 1

Pharmaceutical Device

The present invention is concerned with injection devices for effecting needle insertion into the skin of a patient at a predetermined oblique angle to the surface of the skin.

Injection devices in various forms have been available for many years. Nowadays with slow-release drug devices and e.g. "electronic tags", large solid and semi-solid depots are being inserted into patients.

It is also necessary with many injections to ensure that they are made into the correct tissue, e.g. sub-cutaneously rather than intra-muscularly (or *vice-versa*). Different size needles require different insertion techniques and this typically requires training of e.g. nurses, midwives and health visitors (Supplement to Nursing Times, 14 October 1998) - for a sub-cutaneous injection, short needles of 1.25cm length or less are typically inserted perpendicular to the surface of the skin, whereas longer needles have to be inserted at oblique angles e.g. 45° in order to ensure a subcutaneous injection - injection at the wrong angle could result in muscle damage or other complications. Large solid and semi-solid depot formulations typically require the use of longer than usual needles, meaning that the correct angle of injection becomes more critical, the large object being injected being more likely to protrude into the wrong tissue.

The importance of correct needle insertion into a patient is demonstrated by McIvor, A. *et al.* (1991, The New England Journal of Medicine, 324(26): 1897-1898) who report that improper intramuscular injection techniques performed by trained clinicians occurred at a high rate and could lead to complications including abscesses, induration, erythema, wheal formation, persistent local pain, hemastoma, bleeding and

subcutaneous fat nodularity. This is further confirmed by e.g. Greenblatt, D.J. *et al.* (1976, The New England Journal of Medicine, 295(10): 542-546).

The difficulty involved in giving intramuscular injections is demonstrated by Cockshott, W.P. *et al.* (1982, The New England Journal of Medicine, 307(6): 356-358) who report that studies of gluteal injection sites showed that the majority of injections intended to be intramuscular were actually delivered into fat.

Improper injections can also lead to an altered therapeutic effectiveness of an injected drug, for example an altered activity profile, since different tissues (e.g. fat and muscle) have different characteristics particularly in terms of blood flow and drug absorbtion into the blood stream.

Thus there is a clear need to achieve a correct injection of an object such as a pharmaceutical preparation into a chosen tissue. This is particularly the case when large solid or semi-solid objects are injected.

WO 98/24504 discloses injection devices with deformable needles which are placed perpendicular to the surface of the skin. Upon extension of the needle into the skin, the needle deforms such that it extends at an obtuse angle. However, this requires elastic deformation, pre-stressing of the needle or other mechanical intervention. This is inevitably costly and can create the possibility of mechanical damage occurring to the needle whilst in use, resulting in possible patient discomfort or injury. Such deformable needles can be particularly difficult to use when injecting solid or semi-solid objects which must also deform in order to exit the needle.

US 4380234 discloses a needle attached at an obtuse angle to a disk-like body. The aim of the disk-like body is to hide the needle from sight whilst the needle is being inserted into the skin, as well as hiding it when in place. It also provides points at

which adhesive tapes and the like may be attached to hold the needle in place once inserted, particularly when using infusion devices which may require the needle to be in place for several hours.

The injection of large solid and semi-solid objects can often require the use of large needles of e.g. 5mm diameter. Needle phobias are common among patients, and this is particularly the case with large needles, and can frequently result in refusal by the patient to be injected, or to several attempts being made before an injection is successfully achieved, causing significant patient discomfort and using significant amounts of clinician's time.

Many devices have been developed over the years which hide or camouflage the needle, preventing the patient from seeing it. Such needles and syringes are disclosed in e.g. US 2845065, US 2876770, US 4373526. US 5104386, US 5358489, US 5634906, WO 94/04103, WO 97/04824, WO 98/18512 and EP 0794336.

The present invention improves upon the prior art devices, providing injection devices which effect needle insertion into the skin of a patient at a predetermined oblique angle to the surface of the skin. According to the present invention there is provided an injection device comprising a foot for positioning against the skin of a patient, and a body attached to said foot, the body comprising a needle channel and a syringe having a retractable needle such that upon positioning the foot on the skin of a patient the needle extends along the needle channel and enters the skin at an oblique angle.

By "foot" is meant any supporting means (i.e. appendage) which can be placed on the skin of a patient and which when in place act to securely locate and/or orient the body of the injection device. Thus a foot could extend away from the body and be angled such that it is at an obtuse angle of 135° to the body and when placed against

the skin causes the body to be positioned at an angle of 45° to the surface of the skin. The foot may for example be a disc-like arrangement or it may comprise a rectangular shape extending in one or more directions from the body. The foot may be at an adjustable angle to the body. This allows the same device to be used to insert the needle into the skin of a patient at a range of angles. Thus a clinician may, following a set of instructions provided with the device, take into account factors such as the age, weight, height and sex of the patient in adjusting the angle of injection in order to achieve an optimum angle of injection which will provided the greatest likelihood of insertion of the needle and injection of an object into the correct tissue.

The combination of a foot which first contacts the skin and a body which orients a needle channel, the needle subsequently being inserted into the skin, guarantees the angle at which needle insertion occurs.

The needle of the devices of the present invention must be moveable relative to the foot, thus allowing the needle to be hidden from the sight of the patient. By ensuring the angle at which needle insertion occurs, the use of large needles, particularly those used to inject solid or semi-solid objects such as slow-release drug delivery devices, is greatly simplified. The possibility of patient discomfort resulting from needles extending into e.g. muscle tissue instead of fat is greatly reduced. By helping to ensure the correct injection of objects, their effectiveness is also improved. Naturally, as well as inserting the needle at the correct angle, the needle must also be the correct length. The length of needle is determined by a number of factors including the tissue into which injection is to occur, the age, sex and general health of a patient. The injection of large objects typically requires a precise angle of injection to ensure that the overall depth range is within acceptable limits - too acute an angle of injection may result in an injected object going too deep into a patient and causing complications. Similarly, too obtuse an angle may result in an injected object going too shallow and protruding into

the dermis, causing patient discomfort, possible complications and unsightly skin markings. Thus ensuring a correct angle of injection is very important.

Injections may be sub-cutaneous or intramuscular and so the devices of the present invention may be arranged to effect this. The foot, body and needle channel may be readily angled relative to one-another to give any desired angle of needle insertion, for example 45° or thereabouts. Typically, the body and needle channel will be parallel so that force applied to e.g. a plunger will act to move the plunger and to hold the foot in place. Thus the body may be at a 45° angle to the foot.

The foot may be provided as a removable part of the device, and may be provided in an arrangement such that it may be used in conjunction with a conventional syringe.

The injection devices of the present invention may, of course, be provided in a sterile form, for example within a sterile package.

Also provided is a kit of parts for an injection device according to the present invention. The kit may for example comprise a foot, body and syringe. Other components for such a kit will be readily apparent to one skilled in the art.

The invention will be further apparent from the following description, with reference to the figure of the accompanying drawing, which shows, by way of example only, one form of injection device.

The Figure (Figure 1) shows an injection device according to the present invention.

As can be seen from Figure 1, injection device 10 comprises a foot 20 and body 30 arranged at a 45° angle to one-another. Body 30 contains a needle channel 40 and syringe arrangement 50, having a slidable outer sheath 60, inner sheath 90, and plunger 70. Needle 80 is contained within needle channel 40 held within needle holder 110, and is not outwardly visible. Within needle 80 there is located depot 100.

In use, there are three stages:

i) Needle insertion - foot 20 is placed upon skin 130 of a patient. With foot 20 resting on skin 130, body 30 and needle channel 40 are at a 45° angle to the surface of skin 130. Plunger 70 terminates in push-rod 120. Plunger 70 is advanced until resistance is encountered at first position 140, causing needle 80 and push-rod 120 to advance together and penetrate the surface of skin 130 at a 45° angle to a predetermined depth. Depot 100 is now ready for injection.

ii) Depot injection - plunger 70 is advanced from first position 140 to final position 150. This advances push-rod 120 further, causing depot 100 to extend beyond the tip of needle 80. Needle 80 may now be removed, which facilitates deposition of depot 100.

iii) Needle removal - with plunger 70 in place at final position 150, slidable outer sheath 60 is slid towards the end of plunger 70, retracting with it needle 80. However, this does not cause push-rod 120 to be retracted. Once needle 80 has been successfully removed from the patient, injection device 10 can then be removed from the skin 130 of the patient, removing push-rod 120 at the same time. This two-stage removal of needle 80 and push-rod 120 ensures that whilst needle 80 is being removed, push rod 120 holds depot 100 in place (it could be displaced if needle 80 and push-rod 120 were removed simultaneously).

In an alternative device (not shown), prior to injection depot 100 is held outside of needle 80 in a transparently walled section of injection device 10 so that it is visible to a clinician. Once the clinician has confirmed that depot 100 is contained within device 10, depot 100 may be advanced into needle 80 and the injection proceed.

It will be appreciated that it is not intended to limit the invention to the above example only, many variations, such as might readily occur to one skilled in the art, being possible, without departing from the scope thereof as hereinbefore defined.

CLAIMS

1. An injection device comprising a foot for positioning against the skin of a patient, and a body attached to said foot, the body comprising a needle channel and a syringe having a retractable needle such that upon positioning the foot on the skin of a patient the needle extends along the needle channel and enters the skin at an oblique angle.

2. An injection device according to claim 1, the needle entering the skin at an angle of about 45°.

3. An injection device according to either one of the preceding claims, said body being attached at an oblique angle to said foot.

4. An injection device according to claim 3, the body being arranged at an angle of about 45° to the foot.

5. An injection device according to any one of the preceding claims, being a sub-cutaneous injection device.

6. An injection device according to any one of claims 1-4, being an intramuscular injection device.

7. A kit of parts for an injection device according to any one of the preceding claims.

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Application No: GB 9930338.0 **Examiner:** Susan Chalmers (Mrs)

Claims searched: 1-7 **Date of search:** 2 June 2000

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): A5R: RCQX, RGBA, RGM, RGG

Int Cl (Ed.7): A61M: 5/31, 5/32, 5/46

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
Y	GB 2057269 A	(AUTO-SYRINGE) see eg Figures 2-5 and page 1 line 121 to page 2 line 81	1-7
Y	GB 1286789	(EDWARDS) see eg Figures 1-5, and page 1 lines 20-35 and page 2 lines 66-82	1-7
Y	WO 95/07722 A	(NORTH SHORE) see eg Figure 3 and page 7 line 7 to page 9 line 2	1-7
X	US 5554130	(CREATIVE BIO TECH) see part 30 in the Figures, column 6 lines 26-43 and column 6 line 63 to column 7 line 18	1-7
Y	DE 461457 C	(ISAAK) see whole document	1-7

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

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